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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,718

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Daniel John Daly

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EXAMINER

BERHANU, ETSUB D

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,718	Applicant(s) DALY, DANIEL JOHN	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11,13,14,16-20,24-31,34 and 38-51 is/are pending in the application.
- 4a) Of the above claim(s) 52 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11,20 and 24-31 is/are rejected.
- 7) ☒ Claim(s) 13,14,16-19,34 and 38-51 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 4-42 have been renumbered 5-11, 13, 14, 16-20, 24-31, 34 and 38-53.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 5-11, 13, 14, 16-20, 24-31, 34 and 38-51, drawn to a method and apparatus for measuring changes in an apparent depth of an anterior chamber of an eye to calculate a measure of change in concentration of an analyte of interest, classified in class 600, subclass 318.

Group II, claim(s) 52 and 53, drawn to a method and apparatus for measuring changes in an apparent depth of a section of an eye, classified in class 351, subclass 221.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I requires a change in a refractive index of the anterior chamber and a change in an analyte concentration to be determined while group II is focused on measuring a distance within an eye.

Art Unit: 3768

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Mr. Christopher Lutz on 27 July 2009 a provisional election was made without traverse to prosecute the invention of group I, claims 1-3, 5-11, 13, 14, 16-20, 24-31, 34 and 38-51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 52 and 53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Art Unit: 3768

Claim Objections

5. Claim 7 is objected to because of the following informalities: the term - - the - - should be added between the terms “wherein” and “scanning” in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 fails to provide a further limitation as the analyte of interest would inherently need to be either a naturally occurring or introduced substance. Claim 8 fails to recite a concrete method step and therefore fails to further limit the intended invention.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-3, 5-11, 20 and 24-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In addition to inquiry of whether a claimed method falls within a judicial exception, Supreme Court precedent (*Diamond vs. Diehr*, 450 U.S. 175, 184 (1981); *Parker vs. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).) and recent Federal Circuit decisions, require that a claim drawn to a process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. If neither of these requirements is met by the claim,

Art Unit: 3768

the method is not a patent eligible process under 35 U.S.C. 101 and is improperly directed to non-statutory subject matter. Thus, to qualify as a 35 U.S.C. 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied or positively recite the subject matter that is being transformed. As claims 1-3, 5-11, 20 and 24-31 are not tied to another statutory class, nor do they positively recite subject matter being transformed, they are improperly directed to non-statutory subject matter.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-3, 5, 9, 10, 13 and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims of the copending Application are narrower in scope than the method claims of the current invention. Therefore, any reference meeting the limitations set forth in the claims of the copending Application would also meet the limitations set forth in the claims of the current invention. Furthermore, the method claims of the copending Application require an apparatus such as the apparatus

Art Unit: 3768

disclosed in claims 13 and 16-18 of the current invention. Therefore, one in possession of the method claims of the copending Application would also inherently be in possession of the apparatus as recited in claims 13 and 16-18 of the current invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, an apparatus wherein a processor is adapted to compare a derived apparent depth of an anterior chamber of an eye with a previous reference measurement of the apparent depth of the anterior chamber, use the comparison to determine a change in the refractive index of the aqueous humor and calculate a measure of change in a concentration of an analyte in the aqueous humor based on the determined change of the refractive index, in combination with the other claimed elements.

13. Claims 14 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and to overcome the objections discussed in paragraph 1 above.

14. Claims 34 and 38-51 would be allowable if rewritten to overcome the objections discussed in paragraph 1 above.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Samuels et al.'168 (cited by Applicant) discloses an apparatus and method for measuring glucose through the eye wherein a position in the eye from which multiple spectra are taken is capable of being recorded.

Art Unit: 3768

Hakamata'089 (USPN 6,226,089) teaches measuring glucose through the eye by determining the refractive index of the aqueous humor in the anterior chamber based on different intensities of first and second backscattering light.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB